Section 714 of FDASIA: Registration of Commercial Importers and Good Importer Practices

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Public Meeting: Implementation of Drug Supply Chain Provisions of Title VII of FDASIA
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FDASIA Title VII and Sec. 714

- Title VII: focus on protecting integrity of the drug supply chain and ensuring safety, effectiveness, and quality of imported drugs
- Both sec. 714 and sec. 713 establish new authorities to increase FDA's ability to collect & analyze data to make risk-informed decisions related to imported drugs
- Good importer practices (GIPs) that commercial importers must follow under sec. 714 should in some way reflect the standards that importers must meet under sec. 713

Section 714

- Directs FDA to issue regulations requiring registration of commercial importers of drugs, including a requirement to submit a unique identifier for the principal place of business (under new subsection 801(s) of FD&C Act)
- Directs FDA to establish unique facility identifier (UFI) system for registrants
- Directs FDA to issue regulations on GIPs

Section 714 (cont.)

- Regulations are to be developed in consultation with Customs and Border Protection and issued by July 9, 2015
- FDA may establish exemptions from the requirements of sec. 801(s)

Section 714 (cont.)

- Prohibited act: failure of a commercial importer to register in accordance with sec. 801(s) is a prohibited act under sec. 301
- Discontinuation of registration: FDA must discontinue registration if the commercial importer fails to comply with GIP or registration regulations
- Misbranding: a drug is deemed misbranded under sec. 502(o) if it is imported or offered for import by a commercial importer not duly registered

Issues Concerning Importer Registration

- How to define “commercial importer”
- What exemptions (e.g., types of drugs, types of importers) are appropriate?
- What information should be required?
- What are the benefits of registration and how can potential burdens be minimized?

Good Importer Practices under Sec. 714

- Under sec. 801(s)(2)(A), GIP regulations are to specify the measures an importer must take to **ensure imported drugs are in compliance** with the FD&C Act and the PHS Act
- In establishing effective date of GIP regulations, FDA must provide a **reasonable period of time for importers to comply with GIPs**, "taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product"

Sources for Development of GIP Regulations

January 2009 draft guidance on “Good Importer Practices” issued by ten Federal agencies, including HHS/FDA. Four guiding principles:

- Establishing product safety management program
- Knowing the product and U.S. requirements
- Verifying the product and firm compliance with U.S. requirements throughout supply chain and product life cycle
- Taking corrective and preventive actions

Sources for GIP Regulations (cont.)

Comments from drug and biologics industries on 2009 GIP draft guidance:

- Need to tailor GIPs to drugs & biologics
- Need for consistency with CGMP regulations
- Application to components & finished products
- Expedited entry for “trusted importers”

Sources for GIP Regulations (cont.)

- Comments at this public meeting and those submitted to the public docket
- FDA experience with food importer requirements under the HACCP regulations and the development of the forthcoming proposed rule on foreign supplier verification programs (FSVP)

Issues Concerning GIP Regulations

- Should importers be required to establish drug safety management programs?
- What programs or measures do importers currently follow?
- Should the GIP regulations include requirements for personnel?
- Should importers be required to determine whether it is appropriate to import a particular drug from a particular supplier?

Issues Concerning GIP Regulations (cont.)

- Should importers be required to conduct activities to verify supplier compliance with U.S. requirements? If so, what kind of activities (e.g., auditing, testing)?
- Should there be different requirements for different types of drugs?
- Should importers be required to obtain certificates of analysis?
- Should importers be required to submit a listing of the drugs they import?

Issues Concerning GIP Regulations (cont.)

- How should the GIP regulations reflect or incorporate the standards for admission under sec. 713 of FDASIA?
- How should the GIP regulations reflect the fact that some importers are also drug establishments and therefore would have to comply with both the CGMP and GIP regulations?

Questions?

- We look forward to your comments at this public meeting
- We encourage you to submit written comments to the public dockets on commercial importer registration (FDA-2013-N-0684) and GIPs (FDA-2013-N-0685)

Thank You!

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